

TOM DAVIS, VIRGINIA,
CHAIRMAN

DAN BURTON, INDIANA
CHRISTOPHER SHAYS, CONNECTICUT
ILEANA ROS-LEHTINEN, FLORIDA
JOHN M. McHUGH, NEW YORK
JOHN L. MICA, FLORIDA
MARK E. SOUDER, INDIANA
STEVEN C. LATOURETTE, OHIO
DOUG OSE, CALIFORNIA
RON LEWIS, KENTUCKY
JO ANN DAVIS, VIRGINIA
TODD RUSSELL PLATTS, PENNSYLVANIA
CHRIS CANNON, UTAH
ADAM H. PUTNAM, FLORIDA
EDWARD L. SCHROCK, VIRGINIA
JOHN J. DUNCAN, JR., TENNESSEE
JOHN SULLIVAN, OKLAHOMA
NATHAN DEAL, GEORGIA
CANDICE MILLER, MICHIGAN
TIM MURPHY, PENNSYLVANIA
MICHAEL R. TURNER, OHIO
JOHN R. CARTER, TEXAS
WILLIAM J. JANKLOW, SOUTH DAKOTA
MARSHA BLACKBURN, TENNESSEE

ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074
FACSIMILE (202) 225-3974
MINORITY (202) 225-5051
TTY (202) 225-6852

www.house.gov/reform

HENRY A. WAXMAN, CALIFORNIA,
RANKING MINORITY MEMBER

TOM LANTOS, CALIFORNIA
MAJOR R. OWENS, NEW YORK
EDOLPHUS TOWNS, NEW YORK
PAUL E. KANJORSKI, PENNSYLVANIA
CAROLYN B. MALONEY, NEW YORK
ELIJAH E. CUMMINGS, MARYLAND
DENNIS J. KUCINICH, OHIO
DANNY K. DAVIS, ILLINOIS
JOHN F. TIERNEY, MASSACHUSETTS
WM. LACY CLAY, MISSOURI
DIANE E. WATSON, CALIFORNIA
STEPHEN F. LYNCH, MASSACHUSETTS
CHRIS VAN HOLLEN, MARYLAND
LINDA T. SANCHEZ, CALIFORNIA
C.A. DUTCH RUPPERSBERGER,
MARYLAND
ELEANOR HOLMES NORTON,
DISTRICT OF COLUMBIA
JIM COOPER, TENNESSEE
CHRIS BELL, TEXAS

BERNARD SANDERS, VERMONT,
INDEPENDENT

March 26, 2003

Julie L. Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30333

Dear Dr. Gerberding

I am writing to ask about what appears to be an unanticipated and potentially serious adverse event associated with smallpox vaccination.

According to a health alert sent at 12:15 a.m. this morning to health officials across the country, the military has identified at least ten cases of myopericarditis, an inflammatory condition of the heart, in military vaccinees. According to the alert:

Diagnoses were based on clinical, laboratory, EKG and/or echocardiographic evidence of myocardial or pericardial inflammation. All had onset 6 to 12 days following vaccination; none of the cases have been clinically severe, and all the patients are reported to have recovered fully.¹

As you are aware, at least two cases of myopericarditis have been reported in the civilian population.² This means that there are now 12 cases of a generally rare condition that have occurred after vaccination. While this condition appears not to have caused significant problems so far, it can be associated with lasting damage to the heart and even death.

There are additional reasons to be concerned about the association between myopericarditis and vaccination. Inflammation of the heart has been reported in the past to be a

¹CDC, *Smallpox: People with Known Cardiac Disease Should Not Be Vaccinated*, Health Alert Network (Mar. 26, 2003)

²CDC, *Update on Smallpox Vaccination Program*, Telebriefing Transcript (Mar. 25, 2003).

complication of smallpox vaccination.³ One European study, which was based on a different strain of the vaccine, found a case of myocarditis in every 10,000 vaccinees.⁴ This rate appears to be within an order of magnitude of the frequency of cases already reported in the United States. Moreover, the time period of onset within 6 to 12 days following vaccination is consistent with myopericarditis caused by a virus.⁵

The rate of myopericarditis apparently differs between those in the military getting their first smallpox shot and those getting subsequent shots. According to the health alert, "No cases of myocarditis or pericarditis were detected among approximately 100,000 persons in the military program who were revaccinated."⁶ According to the Department of Defense, approximately 350,000 individuals in total have been vaccinated. This means that there have been 10 cases of myopericarditis among the 250,000 who are first time vaccinees. This is a rate of one case of myopericarditis per 25,000 people vaccinated.⁷

In communications with the public⁸ and press yesterday,⁹ CDC did not mention the military experience with myopericarditis. I understand your desire to defer to the military on what has happened in its vaccination campaign. However, the issue of myopericarditis appears relevant to the civilian vaccination campaign and was included in an alert to state and local health officials. I request that you make appropriate information available to the public about these new findings.

³See, e.g., B. Feery, *Adverse Reactions after Smallpox Vaccination*, Medical Journal of Australia, 180–3 (Aug. 1977).

⁴J. Karjalainen et al., *Etiology of Mild Acute Infectious Myocarditis*, Acta Medica Scandinavica, 65–73 (1983).

⁵For example, myocarditis following influenza virus infection typically occurs within 1 to 2 weeks after the illness starts. Braunwald: *Heart Disease: A Textbook of Cardiovascular Medicine*, 6th ed. (2001).

⁶CDC, *supra* note 1.

⁷The difference between rates of illness among previously vaccinated individuals and first-time vaccinees is noteworthy and suggests that further analysis of this difference might be instructive.

⁸CDC, *Temporary Deferral Recommended for Heart Patients Volunteering for Smallpox Vaccination* (Mar. 25, 2003).

⁹CDC, *supra* note 2.

Julie L. Gerberding, M.D., M.P.H.

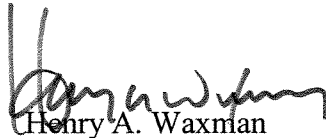
March 26, 2003

Page 3

It is also important that Congress be fully informed about the risks of myopericarditis. A vote in the House on smallpox compensation legislation may occur as early as tomorrow. As you know, I have serious reservations about the adequacy of the Administration's proposal, which is based on my view that individuals injured by the vaccine should be compensated fairly. When Congress considers this important health issue, all available information about the risks of vaccination should be presented to members. Congress should also be informed of any plans to conduct surveillance for myopericarditis in the civilian population.

Overall, the smallpox vaccine has been proven to be very safe. However, as anticipated, there are rare and potentially serious adverse events. The emergence of myopericarditis is another reminder that vaccination is not without risks.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry A. Waxman". The signature is fluid and cursive, with a large initial "H" and "W".

Henry A. Waxman
Ranking Minority Member